

ONE TOUCH® Ultra Test Strips

For Testing Glucose in Whole Blood

IMPORTANT: Please read this information and your ONE TOUCH® Ultra Brand or InDuo™ Brand Owner's Booklet before using ONE TOUCH® Ultra Test Strips.

Intended Use

ONE TOUCH Ultra Test Strips are used with ONE TOUCH® Ultra Brand and InDuo™ Brand Blood Glucose Meters for quantitatively measuring glucose in whole blood. ONE TOUCH® Ultra Brand and InDuo™ Brand Meters read the glucose level of a whole blood sample on a ONE TOUCH Ultra Test Strip. ONE TOUCH® Ultra Brand and InDuo™ Brand Systems are plasma-calibrated to allow easy comparison of results with laboratory methods. ONE TOUCH Ultra Test Strips are for testing outside the body (*in vitro* diagnostic use).

Storage and Handling

- Store the test strip package in a cool, dry place not above 86°F (30°C). Keep away from direct sunlight and heat. Do not refrigerate.
- Store your test strips in their original vial only; do not transfer them to a new vial or any other container.
- After removing a ONE TOUCH Ultra Test Strip from the vial, immediately replace the vial cap and close it tightly.
- Use each test strip immediately after removing it from the vial.
- Write the discard date on the vial label when you first open it. Discard remaining ONE TOUCH Ultra Test Strips 3 months after first opening the vial.
- Avoid getting dirt or food on the top edge.
- Do not use test strips beyond the expiration date printed on the package since they may cause inaccurate results.
- Do not bend, cut, or alter a ONE TOUCH Ultra Test Strip in any way.

Original Vial



(Example)

WARNING: Keep the test strip vial away from children; the cap is a choking hazard. Also, the cap may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

Precautions to Obtain Accurate Results

- **Code the ONE TOUCH Ultra Brand or InDuo Brand Blood Glucose Meter to match the code number printed on the ONE TOUCH Ultra Test Strip vial.**
- **Use only ONE TOUCH Ultra Test Strips with the ONE TOUCH Ultra Brand or InDuo Brand Meter to obtain accurate and consistent results.**
- **If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all instructions described in your ONE TOUCH Ultra Brand or InDuo Brand Owner's Booklet, call your healthcare professional.**
- **Never make significant changes to your diabetes control program or ignore physical symptoms without speaking with your healthcare professional.**



(Example)

Test Procedure for Blood Glucose Measurement

Materials provided: ONE TOUCH Ultra Test Strips.

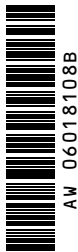
Materials required but not provided: ONE TOUCH Ultra Brand or InDuo Brand Blood Glucose Meter with Owner's Booklet; ONE TOUCH® UltraSoft Adjustable Blood Sampler; new, sterile lancet.

Blood Sample Collection

ONE TOUCH Ultra Test Strips are designed to be used with fresh whole blood. You may obtain a blood drop from either a fingertip or an arm. If you choose to puncture the arm, select a soft, fleshy area (away from bone) that is free of visible veins or excess hair. To obtain a drop of blood, follow these steps:

Step 1: Wash your hands and the puncture site. Use warm, soapy water. Rinse and dry thoroughly.

Step 2: Select and lance a puncture site. Use the ONE TOUCH® UltraSoft Sampler to obtain a drop of blood. If puncturing the arm, you may choose to set the ONE TOUCH UltraSoft Sampler for a greater puncture depth. Do not squeeze excessively on the puncture site. If you use an alcohol swab, make sure that the site is completely dry before lancing it.



Important Information About Arm Testing

- Consult your healthcare professional before you begin using the arm for testing.
- Under certain conditions, blood glucose test results obtained using samples taken from your arm may differ significantly from fingertip samples.
- The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, an insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than arm samples.
- When your blood glucose is falling, testing with a fingertip sample **may** identify a hypoglycemic (low blood sugar) level sooner than a test with an arm sample.
- Use arm samples only for testing prior to, or more than two hours after, meals, insulin dose, or physical exercise.
- Testing performed within two hours after meals, an insulin dose, or physical exercise, or whenever you feel that your glucose levels may be changing rapidly, should be done from the fingertip.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) such as when driving a car, particularly if you suffer from hypoglycemic unawareness (lack of symptoms to indicate an insulin reaction), as arm testing may fail to detect hypoglycemia.
- Use arm or fingertip samples for testing prior to, or more than two hours after, meals, insulin dose, or physical exercise. Routine testing before meals can be done either at the fingertip or the arm.

Blood Glucose Testing

Step 1: Insert test strip. Remove a test strip from the vial. Recap the vial immediately. With the contact bars end first and facing up, insert the test strip into the test port. Push it in firmly until it will go no further. The meter will turn on automatically. All segments will appear briefly on the display. Then “code 12” (example) will appear. Make sure the code number on the display matches the code number on the test strip vial. If the code numbers do not match, code the meter correctly. After the code number, the Δ symbol will appear.

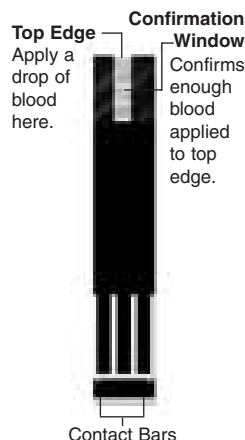
Step 2: Apply sample. Obtain a round drop of blood. **The blood sample must be at least 1 microliter in volume** (● actual size) or you may get an inaccurate test result. While the Δ symbol is displayed, **touch and hold a drop of blood to the TOP EDGE of the test strip, where it meets the narrow channel.** Do not push your finger against the test strip or try to apply a smeared sample. Hold the blood drop to the TOP EDGE of the test strip until blood has **completely filled** the confirmation window before the meter begins to count down. If the confirmation window does not fill completely before the meter begins to count down, do not add blood to the test strip; discard the test strip and retest. If you have trouble filling the test strip, contact LifeScan Customer Services for assistance.

Step 3: Accurate results in just 5 seconds. Your blood glucose result will appear on the display in just 5 seconds. Blood glucose results are automatically stored in the meter memory. Turn the meter off by removing the test strip.

For detailed information on the test procedure and coding your meter, please refer to your ONE TOUCH Ultra Brand or InDuo Brand Owner's Booklet.

Test Results

- Blood glucose test results are shown on the meter as either milligrams of glucose per deciliter of blood (mg/dL) or millimoles of glucose per liter of blood (mmol/L), depending on which unit of measurement you have selected.
- ONE TOUCH Ultra Brand and InDuo Brand Meters display results between 20 and 600 mg/dL (1.1–33.3 mmol/L). If your test result is lower than 20 mg/dL (1.1 mmol/L), “LL” will appear on the meter display. This indicates severe hypoglycemia (low blood glucose).



You should immediately treat hypoglycemia as recommended by your healthcare professional. If your test result is above 600 mg/dL (33.3 mmol/L), “HI” will appear on the meter display. This indicates severe hyperglycemia (high blood glucose). You should seek immediate medical assistance.

- When your blood glucose result is above 240 mg/dL (13.3 mmol/L) or reads “HI,” “ketones?” will appear on the meter display. This message does not mean that the system detected ketones but that testing with a ketone strip may be advisable.

Range of Expected Values

Blood glucose monitoring requires the help of a health-care professional. Together you can set your own range of expected blood glucose values, arrange your testing times, and discuss the meaning of your blood glucose results.

Expected blood glucose levels for people without diabetes:¹

Time	Range, mg/dL	Range, mmol/L
Before breakfast	70–105	3.9–5.8
Before lunch or dinner	70–110	3.9–6.1
1 hour after meals	Less than 160	Less than 8.9
2 hours after meals	Less than 120	Less than 6.7
Between 2 and 4 AM	Greater than 70	Greater than 3.9

If You Get Unexpected Results:

IMPORTANT: Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), you should contact your healthcare professional and follow his or her treatment advice.

Quality Control: Checking the System

Do a Control Solution Test:

- When you begin using a new vial of test strips
- At least once a week
- Whenever you suspect that the meter or test strips are not working properly
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate
- If you drop the meter

When control solution is applied to the top edge of the ONE TOUCH® *Ultra* Test Strip, you should get results within the expected range printed on the test strip vial. If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:

- Error in performing the test
- Failure to shake the control solution vial well enough (must shake vigorously)
- Expired or contaminated control solution
- Improper coding of the meter
- Test strip deterioration
- Meter malfunction
- Control solution that is too warm or too cool
- Failure to discard the first drop of control solution

IMPORTANT: If you continue to get ONE TOUCH® *Ultra* Control Solution test results that fall outside the range printed on the vial, the ONE TOUCH® *Ultra* Brand or InDuo™ Brand System may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result that falls within the range. If you continue to have problems, call LifeScan Customer Services at 1 800 227-8862.

Limitations

ONE TOUCH *Ultra* Test Strips give accurate results when the following limitations are observed:

- The test strips should not be used for the testing of newborns.
- The test strips are for single use only. Do not reuse.
- The test strips are specific to D-glucose and do not react to other sugars which may be present in blood.
- Use only fresh capillary whole blood. Do not use serum or plasma.
- Extremes in hematocrit may affect test results.² Hematocrit levels less than 30% may cause falsely high readings and hematocrit levels greater than 55% may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professional.
- ONE TOUCH *Ultra* Test Strips may be used at altitudes up to 10,000 feet without an effect on test results. Accurate results were demonstrated in clinical studies performed at altitudes up to 1,640 feet and in studies simulating altitudes up to 10,000 feet.

Healthcare professionals—please note these additional limitations:

- Fresh capillary blood may be collected into heparin-containing test tubes if the blood is used within minutes. Do not use other anticoagulants or preservatives.

- Interferences:** Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Patients undergoing oxygen therapy may yield falsely lower results.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis). Critically ill patients should not be tested by blood glucose meters.
- Lipemic samples:** Cholesterol levels up to 600 mg/dL and triglycerides up to 400 mg/dL do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with ONE TOUCH *Ultra* Brand and InDuo Brand Systems.

Test Principle

Glucose in the blood sample mixes with special chemicals on the test strip and a small electrical current is produced. This current is measured by the ONE TOUCH® *Ultra* Brand or InDuo™ Brand Meter and displayed as your blood glucose result. The strength of these currents changes with the amount of glucose in the blood sample.

Reagent Composition

Each ONE TOUCH *Ultra* Test Strip contains: Glucose oxidase (*Aspergillus niger*) ≥0.8 IU; other ingredients (mediator, buffer, etc.) ≥0.05 mg. The vial or vial cap contains approximately 1.4 g silica gel or 2.8 g of molecular sieve.

Performance Characteristics

The performance of ONE TOUCH *Ultra* Test Strips has been evaluated both in laboratory and in clinical tests.²

Measurement range: The measurement range of the ONE TOUCH *Ultra* System is 20 to 600 mg/dL (1.1–33.3 mmol/L).

Accuracy: The accuracy of the ONE TOUCH *Ultra* System was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by 117 diabetic patients at 3 clinical centers:

Slope	0.986
y-intercept	-5.5 mg/dL
Correlation coefficient (r)	0.984
No. of samples	117
Range tested	36.4–434 mg/dL

This study shows that the ONE TOUCH *Ultra* System compares well with a laboratory method.

Precision:

Within Run Precision	Blood _{av} 45 mg/dL	CV = 3.2%
	Blood _{av} 77 mg/dL	CV = 2.0%
	Blood _{av} 129 mg/dL	CV = 2.1%
	Blood _{av} 220 mg/dL	CV = 1.8%
	Blood _{av} 364 mg/dL	CV = 1.6%

Total Precision	Control 44 mg/dL	CV = 4.4%
	Control 171 mg/dL	CV = 2.6%
	Control 366 mg/dL	CV = 2.4%

This study shows a variability from strip to strip in blood tests of 3.2% or less.

IMPORTANT: For a complete description of operating instructions and other important technical information, please refer to your ONE TOUCH® *Ultra* Brand or InDuo™ Brand Owner’s Booklet. IF YOU HAVE QUESTIONS ABOUT THE USE OF ANY LIFESCAN PRODUCT, PLEASE CONTACT LIFESCAN CUSTOMER SERVICES AT 1 800 227-8862.

References

- Krall, L.P., and Beaser, R.S.: *Joslin Diabetes Manual*. Philadelphia: Lea and Febiger (1989), 138.
- Data on file.

OUR COMMITMENT TO YOU:

Our goal is to provide you with quality healthcare products and dedicated customer service. If you are not fully satisfied with this product, we offer a No-Risk, Money-Back Guarantee and will refund your purchase within 30 days. Please contact us regarding a refund or with questions about the use of any LifeScan product. For assistance, please contact LifeScan Customer Services at 1 800 227-8862.